

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UMB BANK, N.A., as Trustee,

Plaintiff,

Case No. 15 Civ. 08725 (GBD) (RWL)

- against -

SANOFI,

Defendant.

**PLAINTIFF'S OBJECTIONS TO PART TWO OF THE MAGISTRATE JUDGE'S
APRIL 12, 2018 REPORT AND RECOMMENDATION ON THE TRUSTEE'S MOTION
FOR SUMMARY JUDGMENT REGARDING ITS 7.6(a) AUDIT RIGHT**

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These Objections are respectfully submitted on behalf of Plaintiff UMB Bank, N.A., as Trustee (the “Trustee”).

In his Report and Recommendation (“R&R”) (ECF 185), Magistrate Judge Lehrburger recommends that the Court grant the Trustee’s Motion for Summary Judgment regarding Claim VI of the Second Amended Complaint for declaratory judgment regarding the Trustee’s audit rights under Section 7.6(a) of the CVR Agreement, finding that, as a matter of law, the Trustee is entitled to an independent audit of Sanofi’s product sales numbers. The Trustee objects only to that aspect of the R&R that recommends that enforcement of this audit right should be deferred.

THE RELEVANT FACTS

In 2010, Sanofi, a large French pharmaceutical company, made a tender offer to acquire Genzyme, a leading U.S. biotechnology firm, for \$69 cash per share (~ \$20 billion). The Genzyme Board rejected the Sanofi offer as inadequate. The difference in valuation was largely attributable to Lemtrada, a drug that had been approved by the FDA for treating leukemia and was in Phase III clinical trials for treating multiple sclerosis (“MS”). Genzyme thought that Lemtrada would be a blockbuster with billions in annual sales because, unlike traditional MS treatments that require daily/weekly dosing regimens, Lemtrada had a unique treatment cycle of only two annual treatment courses.¹

To bridge a \$4 billion valuation gap, Sanofi increased its cash offer, and agreed to issue to Genzyme shareholders one Contingent Value Right (“CVR”) for each public share tendered. The CVRs are securities, traded on NASDAQ. Sanofi established an express trust for the benefit of the CVR Holders. Plaintiff UMB Bank is Trustee under the CVR Agreement.

¹ Studies have shown that a significant percentage of those patients treated with Lemtrada have shown no symptoms of MS for five years.

The CVR Agreement is governed by New York law (CVR Agreement § 1.10), and in relevant part requires Sanofi to use “Diligent Efforts to achieve” certain Milestones with respect to the development and commercialization of Lemtrada (*Id.* § 1.10). Four of those Milestones are sales-based. Section 5.4(a) of the CVR Agreement (“Reports by Company”) requires Sanofi, throughout the ten-year life of the CVR Agreement, to provide the Trustee with quarterly Product Sales Statements reflecting its sales of Lemtrada. The Trustee and the CVR Holders are not required to merely accept whatever information Sanofi presents. The CVR Agreement entitles the Trustee “to examine the books, records and premises of [Sanofi]” either personally or “by agent” (*id.* at § 4.2(f)), and to an independent audit “to verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein.” *Id.* at § 7.6(a). Section 7.6(a) of the CVR Agreement provides in relevant part:

“Upon the written request of the Acting Holders (but no more than once during any calendar year), and upon reasonable notice, [Sanofi] shall provide an independent certified public accounting firm of nationally recognized standing jointly agreed upon by the Acting Holders and [Sanofi] (failing agreement on which each shall designate an independent public accounting firm of its own selection, which firms shall in turn appoint an independent public accounting firm for such purpose) (the ‘Independent Accountant’) with access during normal business hours to such of the records of [Sanofi] as may be reasonably necessary to verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein for any period within the preceding three (3) years that has not previously been audited in accordance with this Section 7.6. The fees charges by such accounting firm shall be paid by [Sanofi].”

An independent audit of the Sanofi Product Sales Statements will obviate the need for a great deal of discovery in this action and for expert testimony concerning the accuracy of Sanofi’s Product Sales Statements, streamlining both pretrial preparation and the trial itself. *See* CVR Agreement § 7.6(a) (“The Independent Accountant shall disclose to the Acting Holders any matters directly related to their findings and shall disclose whether it has determined that any

statements set forth in the Product Sales Statements are incorrect. The Independent Accountant shall provide [Sanofi] with a copy of all disclosures made to the Acting Holders.”).

The Trustee issued a demand that Sanofi comply with the audit provisions of Section 7.6(a). *See* R&R at 4, citing Wilkinson Decl. ¶ 11 (ECF No. 137). Sanofi refused. *Id.* On October 6, 2017, the Trustee moved for partial summary judgment as to Count VI of the Second Amended Complaint regarding the audit rights under Section 7.6(a) of the CVR Agreement. *See* ECF 134-138. Following the completion of all briefing (ECF 134-138; ECF 153-155; ECF 161), the Court referred the motion to Magistrate Judge Lehrburger for report and recommendation (ECF 169).

Following oral argument, Magistrate Judge Lehrburger issued the R&R, recommending that the Court grant the Trustee’s motion for summary judgment, finding “[t]he parties do not dispute the meaning of Section 7.6(a) of the CVR Agreement,” and that Section 7.6(a) “clearly and unambiguously gives UMB, as trustee, the right upon written request to have Sanofi conduct an independent audit of Lemtrada sales figures and to do so at Sanofi’s expense.” (R&R at 7).

However, the R&R goes on to state that “[w]hile summary judgment on the merits of UMB’s audit claim is warranted, it does not necessarily follow that UMB is entitled to immediate entry and enforcement of that judgment.” (R&R at 14). The Magistrate Judge found that “the information that will be generated by the audit is information that will be flushed out through the litigation” (*Id.* at 15), and that “deferring enforcement of its audit right pending litigation that seeks to discover and develop the same sales data does not pose any significant risk of harm.” (*Id.* at 16).

Following oral argument of the motion, Sanofi had provided the Trustee with eleven top-level spreadsheets purportedly representing the first level of information below that contained in

the Product Sales Statements for each of eleven quarters. In other words, Sanofi has provided a spreadsheet one level down from the Product Sales Statements and is refusing to provide the information that is rolled up to that level – in effect demanding that the Trustee accept at face value the numbers that Sanofi provides. The CVR Agreement requires otherwise. These top-level spreadsheets do not allow the verification of the information that is rolled up into the Product Sales Statements and the adjustments to that information made by Sanofi.²

The Trustee requested that Sanofi provide discovery reasonably necessary to verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein. Sanofi refused. The Trustee then requested that Magistrate Judge Lehrburger reconsider the second aspect of the R&R. *See* ECF 186. The Magistrate Judge temporarily withdrew the R&R (ECF 187), considered the Trustee's request (ECF 186) and Sanofi's response (ECF 188), and on April 24, 2018 reinstated the R&R without revision. *See* ECF 189.

The Trustee has a clear contractual right to an independent audit of Sanofi's Product Sales Statements wholly separate from its right to discovery in this action. An audit is functionally very different from litigation discovery and litigation discovery is not a proper substitute for an independent audit. Making matters worse, Sanofi refuses to provide the discovery necessary to assess the accuracy of its Product Sales Statements, leaving the Trustee

² An exemplar quarterly Product Sales Statement is attached hereto as Appendix A. The top-level spreadsheet corresponding to this Product Sales Statement recently produced by Sanofi is attached hereto as Appendix B. The spreadsheet is comprised of the aggregation of information – none of which is available to the Trustee in any intelligible form so as to permit the verification of information to which the Trustee is plainly entitled. Moreover, the top-level summary numbers provided by Sanofi are net numbers, after taking into effect adjustments (currency translations; product sales discounts; rebates; *etc.*), and do not permit the Trustee to see how Sanofi has changed the actual sales numbers for its reporting purposes. The CVR Agreement requires that “the amounts in the Product Sales Statements shall be calculated in accordance with [International Financial Reporting Standards].” CVR Agreement at 13. The Trustee cannot determine that this is so from top-level spreadsheets themselves. *See* ECF 186 at n.1.

without the means to verify the key information on which achievement of the Product Sales Milestones is based. The R&R properly recognizes the Trustee's absolute right under Section 7.6(a) to an independent audit, but a refusal to enter final judgment under Rule 54(b) will cause irreparable harm to the Trustee's audit rights as guaranteed by the CVR Agreement.

LEGAL STANDARD

On dispositive motions “[t]he district judge must determine *de novo* any part of the magistrate judge's disposition that has been properly objected to.” Fed. R. Civ. P. 72(b)(3). The district judge may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions. *Id.*

ARGUMENT

I. The Magistrate Judge properly recommends that the Trustee is entitled to summary judgment on its contractual right to an audit of the Sanofi Product Sales Statements.

The Magistrate Judge correctly recommends that the Trustee is entitled, as a matter of law, to summary judgment on the merits of its claim for an audit under Section 7.6(a) of the CVR Agreement. As noted in the R&R, “[t]he parties do not dispute the meaning of Section 7.6(a) of the CVR Agreement.” R&R at 7. The provision “clearly and unambiguously” gives the Trustee “the right upon written request to have Sanofi conduct an independent audit of sales figures and to do so at Sanofi's expense.” *Id.*

The Magistrate Judge also correctly rejected Sanofi's argument that factual disputes still existed around the Trustee's 7.6(a) right. The dispute between the parties about the proper Launch Date of Lemtrada under the terms of the contract has no bearing on the 7.6(a) audit right. R&R at 8 (“Section 7.6(a) makes no mention of Lemtrada's launch date and is not dependent on

the launch date.”). The Launch Date is “irrelevant to the motion” and “does not foreclose summary judgement.” R&R at 13.

Similarly, the Magistrate Judge correctly rejected Sanofi’s affirmative defense of bad faith. “The problem with Sanofi’s argument is that Sanofi does not have a viable bad faith defense against UMB’s invocation of its [audit] rights under Section 7.6(a).” R&R at 9. Generally, a party cannot breach a contract’s implied obligation of good faith by exercising a contractual right. R&R at 10 (citing *Suthers v. Amgen Inc.*, 441 F. Supp.2d 478, 485 (S.D.N.Y. 2006), and the motivations of UMB or the CVR shareholders are “irrelevant to UMB’s audit claim.” R&R at 13.

II. The Trustee’s Section 7.6(a) claim is separable from the remaining claims in this action and a prime candidate for final judgment.

In briefing and at oral argument the parties focused on the merits of the Trustee’s motion. Before the R&R was issued, neither party nor the Magistrate Judge brought up the issue of whether, if the Trustee should prevail, an entry of final judgment was proper under Fed. R. Civ. P. 54(b), and the Magistrate Judge did not have the benefit of the parties’ briefing of the issue.

A district court has authority to enter final judgment for fewer than all claims in an action if “there is no just reason for delay.” Fed. R. Civ. P. 54(b). This rule “was originally adopted in view of the wide scope and possible content of the newly created ‘civil action’ in order to avoid the possible injustice of a delay in judgment of a distinctly separate claim to await adjudication of the entire case.” Fed. R. Civ. P. 54 Notes of Advisory Committee on Rules—1946 Amendment. Here, there is no good reason for delay. On the contrary, delay will only continue to cause unjust injury to the Trustee and the CVR Holders that the Trustee represents.

“In a case involving multiple claims, the court should not enter final judgment dismissing a given claim unless that claim is separable from the claims that survive.” *Cullen v.*

Margiotta, 811 F.2d 698, 711 (2d Cir.), *cert. denied*, 483 U.S. 1021 (1987)). The Section 7.6(a) audit right is entirely separable from the remaining claims in the action and its execution now will obviate the need for a great deal of discovery in this action and for expert testimony concerning the accuracy of Sanofi’s Product Sales Statements, streamlining both pretrial preparation and the trial itself. *See Star Funding, Inc. v. Tire Centers, LLC*, 717 F. App’x 38, 41 (2d Cir. 2017) (Upholding Rule 54(b) final judgment entry despite lack of explanation from the district court because “the issue in this appeal is separable from the rest of the case, and it is unlikely that we will be asked to revisit the same issue in a subsequent appeal.”); *Domino Media, Inc. v. Kranis*, 9 F. Supp. 2d 374, 390 (S.D.N.Y. 1998) (Kaplan, J.), *aff’d*, 173 F.3d 843 (2d Cir. 1999) (granting Rule 54(b) judgment in fraudulent conveyance case because remaining claims were “factually independent” of the claim for which summary judgment had been granted).

Courts especially look to whether the Rule 54(b) decision “will make possible a more expeditious and just result for all parties.” *L.B. Foster Co. v. Am. Piles, Inc.*, 138 F.3d 81, 87 (2d Cir. 1998) (quoting *Gumer v. Shearson, Hammill & Co.*, 516 F.2d 283, 286 (2d Cir. 1974)). “Where the court has directed the entry of final judgment as to claims that are separable from and independent of the unresolved claims, and has provided an informative explanation, its conclusion that there is no just reason for delay is entitled to ‘substantial deference.’” *L.B. Foster Co. v. Am. Piles, Inc.*, 138 F.3d 81, 86–87 (2d Cir. 1998) (quoting *Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 10 (1980)) (upholding Rule 54(b) judgment out of concern for expeditious proceedings despite the independence of the claims being “a close question”).

Here the Trustee’s claim is independent of the remaining claims. Whether or not Sanofi is later found to have breached its obligations to use Diligent Efforts to achieve the Milestones is unrelated to the Trustee’s Section 7.6(a) audit right. The Trustee is entitled to an independent

audit of Sanofi's Product Sales Statements regardless of the existence or outcome of the claims regarding the failure to pay Milestones. As the R&R rightly held, there are no relevant factual disputes about the Trustee's 7.6(a) audit claim. It is easily separable and factually independent and a Rule 54(b) final judgment should be entered for this claim.

III. Delay in entering final judgment will cause unjust harm to the Trustee.

The R&R states that "deferring enforcement of [the Trustee's] audit right pending litigation that seeks to discover and develop the same sales data does not pose any significant risk of harm." R&R at 16. Respectfully, that is not the case.

- a. *The Trustee's contractual right to an audit under Section 7.6(a) is not equivalent to the rights of discovery afforded a civil litigant.*

The right to discovery is bestowed upon any civil litigant who is able to overcome a motion to dismiss. No agreement prior to the litigation is required between the parties for either party to be entitled to discovery. The audit right of the Trustee as bestowed by Section 7.6(a) of the CVR Agreement cannot be confused with the discovery that the Trustee may be entitled to pursuant to claims against Sanofi. The Trustee's right to an independent audit is a contractual right to which Sanofi agreed when it signed the CVR Agreement. This audit right is not the same as the discovery that arises in the context of litigation over missed Milestones.³

Even where the Trustee exercises its right under the CVR Agreement to bring suit for missed Milestone payments (or anything else), that does not extinguish the other rights of the

³ To highlight how the audit and discovery are not the same, consider the time periods for each. Outside of some isolated exceptions, discovery on the claims in this case has been limited to a period up until July 2016. But the audit under Section 7.6(a) covers all Product Sales Statements, which Sanofi has made every quarter since 2011 and continues to make now, the most recent of which was released on April 26, 2018. These post-July 2016 Product Sales Statements are clearly subject to audit under Section 7.6(a), but Sanofi has not produced any discovery materials regarding them because they are outside the general discovery time period for the Milestone claims. The Trustee cannot flush out the material surrounding these later Product Sales Statements via discovery, because discovery has not covered these time periods. Section 7.6(a) audits were never meant to be limited by the narrow constraints of litigation discovery for other claims brought under the CVR Agreement.

Trustee under the CVR Agreement. On the contrary, the CVR Agreement specifically provides that the Trustee's powers under the CVR Agreement are cumulative and asserting one right under the CVR Agreement (*e.g.*, lawsuit for failure to pay Milestones) does not prevent the assertion of any other right (*e.g.*, right to an audit under Section 7.6(a)). *See* CVR Agreement § 8.8 (“[N]o right or remedy herein conferred upon or reserved to the Trustee or to the Holders is intended to be exclusive of any other right or remedy.”). In addition, the Trustee's rights under the CVR Agreement are specifically articulated as *additional* to any other rights the Trustee may have by right of law, such as civil litigation discovery rights. *Id.* at § 8.8 (“[E]very right and remedy shall, to the extent permitted by Law, be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at Law or in equity or otherwise.”). The CVR Agreement also specifically provides that the Trustee could assert any of its CVR Agreement rights concurrently with one another: “The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other appropriate right or remedy.” *Id.*

The current claims by the Trustee regarding failed Milestone payments – and the discovery attendant to those claims – impose no limitation on the Trustee's right to an audit under Section 7.6(a).

- b. *The nature of an audit as contemplated by Section 7.6(a) is significantly different than litigation discovery.*

In both process and substance, an audit is very different than discovery in civil litigation. An audit is a cooperative, iterative, accountant (not lawyer) driven process with real time back and forth between the auditor and knowledgeable accounting employees of the company. Lawyers need not be involved. Any failure of cooperation by Sanofi in connection with the audit would itself be a breach of contract. Audits such as the one provided for in the CVR Agreement

are common in earn-out and royalty agreements and there are accountants and industry standards dedicated to these audits.

In contrast, civil discovery in an adversary process is lawyer driven, involving demands, objections and responses, formal document productions and timed depositions, all stretching out over months. Proportionality is taken into account. *See Rembrandt Diagnostics, LP v. Innovacon, Inc.*, 2018 WL 692259, at *8 (S.D. Cal. Feb. 2, 2018) (Denying request for information concerning sales figures: “Plaintiff’s argument that this type of information would be provided in an audit lacks merit, this is discovery, not an audit.”).

Discovery in the adversary process is not an efficient means by which to obtain the information reasonably necessary to verify Sanofi’s Product Sales Statements. In any event, Sanofi has made clear to that it will not even provide in discovery the basic documentation needed to do a reasonably audit-equivalent analysis. After the issuance of the R&R, the Trustee sought to arrange for it or its representative to “inspect, copy, test, or sample . . . any designated documents or electronically stored information” sufficient to “verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein.” *See* ECF 186, Ex. A. Sanofi has rejected this request, and instead cited the Bates numbers of 11 documents that had been produced to the Trustee (nearly all on March 30, 2018 – after the briefing and argument on this motion before the Magistrate). *Id.* All 11 documents are top-level spreadsheets, and are insufficient to verify the information underlying the Product Sales Statements and the adjustments from gross to net made thereto. These spreadsheets were never meant to be used in isolation and are severely handicapped when taken out of the systems in which they operate. They contain references to accounting procedures and ledger reports that are not provided that are vital to understanding how the figures were

calculated. Some figures are hard wired into the spreadsheets with no explanation for their origin. Other entries are vague in other ways. For example, in the 4th quarter 2015 spreadsheet for the United States (SAN-CVR 017766451), \$5.3 million is deducted from reported gross sales (and from reported Product Sales) for “Other rebates.” This represents the lion’s share of the gross to net deductions in this quarter, but no explanation is given for it other than the generic title.⁴

Even if Sanofi cooperated in providing discovery of the information underlying its Product Sales Statements – and it is not – discovery is a poor substitute for the information obtained in the independent audit provided for in Section 7.6(a). *See Baratta v. Homeland Housewares, L.L.C.*, 2011 WL 13152462, at *1 (S.D. Fla. July 26, 2011), *report and recommendation adopted*, 2011 WL 13152463 (S.D. Fla. Aug. 17, 2011) (enforcing a contractual audit right regarding possible royalty payment and granting auditor access to Company’s electronic accounting systems to verify information).

- c. *Substituting discovery for the Trustee’s 7.6(a) audit unjustly shifts the cost burden in contradiction to the plain language of Section 7.6(a), thereby harming the Trustee.*

The R&R concluded that “the information that will be generated by the audit is information that will be flushed out through the litigation” and therefore there is no harm to the Trustee in delaying the audit until after discovery and trial. *See* R&R at 15. Even if Sanofi provided the information reasonably necessary to verify its Product Sales Statements – and it has not, and is refusing to do so – the harm to the Trustee is manifest.

⁴ These insufficiencies are only a sampling of ways that the discovery documents produced by Sanofi are insufficient to “verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein” as called for in an audit under Section 7.6(a).

First, as discussed above, discovery is a poor substitute for an independent audit on which the parties can rely in lieu of experts in the presentation of this case.

Second, as the R&R correctly points out, Sanofi is required to conduct an independent audit of the Product Sales Statements and to do so “at Sanofi’s expense.” R&R at 7. This cost bearing by Sanofi is a material contract term to which Sanofi and the Trustee agreed. Delaying final judgment and requiring the Trustee to instead seek to obtain information via discovery reverses the cost burden from what was agreed to by the parties in the CVR Agreement. Relegating the Trustee to the adversary discovery process effectively denies the Trustee the benefit of its contract. *See* Fed. R. Civ. P. 54 Notes of Advisory Committee on Rules—1946 Amendment (Rule 54(b) “was originally adopted in view of the wide scope and possible content of the newly created ‘civil action’ in order to avoid the possible injustice of a delay in judgment of a distinctly separate claim to await adjudication of the entire case.”).

d. Delaying the audit until after the end of litigation is wasteful and inefficient

Delaying the audit will not create litigation efficiency, but the opposite.⁵ Due to the delay in the audit, the Trustee will be required to hire its own accounting expert to examine, to the extent possible through limited discovery means, the Product Sales Statements and the figures and calculations they contain. This will require considerable expense. In addition, Sanofi will no doubt hire its own expert to rebut whatever the Trustee’s expert has to say about the acceptability of the accounting methods employed in calculating the relevant figures.⁶ This

⁵ The litigation efficiency that results from the audit is a bonus. The Trustee is unequivocally entitled to the audit at its request without regard to convenient timing or efficiency. But the indisputable fact is that having the independent audit done now will streamline final pretrial preparation and the trial itself.

⁶ The R&R states that “neither party was willing to fully commit to accepting the findings of the Independent Auditor for the purposes of this litigation.” R&R at 15. This is simply not true. If the Trustee was not clear at the recent hearing (*see* 3/28/18 Transcript (ECF No. 183) at 75: 7-12, 76: 4-6, 19-

is a doubling of the effort and expense from what would be the case if an independent accountant were allowed to conduct an audit as described in Section 7.6(a).

Delaying the entry of final judgment on the Trustee's audit right only delays the actual Section 7.6(a) audit to which the Trustee is entitled. It does not and cannot extinguish that right. As proposed in the R&R, however, the Trustee would be given final judgment on that claim only after all the other claims in this case have been tried to completion. Thus after extensive document discovery, depositions, expert testimony, and trial regarding the sales of Lemtrada, only then would the Trustee be entitled to the independent audit of the Lemtrada sales figures contained in the Product Sales Statements. Requiring the Trustee to wait until then for the audit, and conversely, requiring Sanofi to undergo and pay for an audit after trial, is the definition of inefficiency.

CONCLUSION

The Court should adopt the R&R as it relates to the granting of the Trustee's motion for summary judgment regarding Claim VI of the Second Amended Complaint for declaratory judgment and the Trustee's independent audit rights under Section 7.6(a) of the CVR Agreement, finding that, as a matter of law, the Trustee is entitled to an independent audit of Sanofi's Product Sales Statements. The Court should, however, reject the R&R's recommendation that entry of judgment should be withheld. The Court should, instead, exercise its power under Rule 54(b) and enter judgment for the Trustee as to Claim VI of the Second Amended Complaint since there is no good reason for any deferral of the exercise of that independent audit right, the completion of which will facilitate and expedite remaining discovery

22, 77:23-78:3, 79: 20-24, 80:3-4, 14-25, 81:1-11), let us be clear now: the Trustee agrees to accept the unqualified factual findings of the Section 7.6(a) Independent Accountant. That Sanofi opposes an independent audit of the product sales numbers that it has provided speaks volumes.

and the trial of this action. The Court should also order Sanofi to cooperate forthwith in the independent audit pursuant to Section 7.6(a) of the CVR Agreement.

Dated: May 8, 2018

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